

Cholesterol Protocol

2006



Utah Department of Health
Heart Disease and Stroke Prevention Program
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Blood Cholesterol Measurement Standardization Class

The Cardiovascular Program offers classes in blood cholesterol measurement for: (1) community health professionals (2) hospital professionals and (3) students.

The standardization process includes:

1. Attending a presentation on blood cholesterol measurement.
2. Passing the blood cholesterol measurement standardization written test.
3. Passing a practicum in blood cholesterol measurement.

Note: It is suggested that all employees involved in obtaining blood specimens or performing any laboratory test involving blood be immunized against Hepatitis B.

Standardization must be renewed every two years.

For further information, contact the Heart Disease and Stroke Prevention Program, Utah Department of Health, P.O. Box 142107, Salt Lake City, UT 84114-2107 / Telephone: 801-538-6142



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I. GENERAL INFORMATION

A. Importance of Hypercholesterolemia (High Cholesterol)

1. Increased blood cholesterol levels, more specifically increased levels of low density lipoprotein (LDL) cholesterol, are causally related to an increased risk of coronary heart disease (CHD). Coronary risk rises progressively with cholesterol level particularly when cholesterol levels rise above 200 mg/dl. There is also evidence that lowering total and LDL cholesterol levels will reduce the incidence of CHD.
 - a. Persons with both hypercholesterolemia and hypertension (high blood pressure) have twice the risk of a heart attack.
 - b. Persons who have hypercholesterolemia and smoke have a five-fold risk for a heart attack.
2. Results from survey data collected by the State Cardiovascular Program have shown half of all adults in Utah have cholesterol levels at or above 200mg/dl which is above the desirable level. The same finding has been shown nationally.
3. Most coronary heart disease is due to blockages in the arteries that supply blood to the heart muscle. Studies have shown that elevated levels of blood cholesterol, whether caused by genetic defects or dietary excesses, lead to the development of atherosclerosis and coronary heart disease.
4. The chances of developing coronary heart disease increase in proportion to the amount the cholesterol is elevated, especially for values over 200 mg/dl. If other risk factors are present, the risk for heart disease increases. *For each 1% reduction in total blood cholesterol, there is a 2% reduction in heart disease risk.*

B. Characteristics of Hypercholesterolemia

1. The liver produces all of the cholesterol the body needs to function normally.
2. The blood cholesterol value is influenced by genetic factors, and by dietary cholesterol obtained from food of animal origin and other saturated fats consumed in the diet.

C. Definitions

1. *Cholesterol:* A fatty wax-like substance circulating in the blood. It is a building block for cell walls and is necessary for production of essential sex hormones, Vitamin D, and digestive juices. It is also a component of the myelin sheath that insulates nerve fibers.
2. *Lipoprotein:* Cholesterol does not circulate in the blood as a free lipid, instead it must be packaged with a protein compound to form lipoprotein. There are five plasma lipoproteins which carry cholesterol through the blood.



3. *Lipid:* It is a fat or fat-like substance characterized by being insoluble in water. Lipids are easily stored in the body and serve as a source of fuel. They are an important constituent of all cells and also have other biological functions.
- a. The two lipoproteins receiving primary focus in the atherosclerotic process are:
- (1) *High Density Lipoprotein (HDL)* - These particles are 50% protein by weight and only contain a small portion of cholesterol and triglycerides. They are the smallest in size of all lipoprotein. They are often called the “good” cholesterol since they clear cholesterol from the arteries. The National Cholesterol Education Program (NCEP) has recommended the following guidelines for HDL levels: Normal range for HDL in the bloodstream is greater than 40 mg/dl. Below this level is considered a risk factor for coronary heart disease.
 - (2) *Low Density Lipoprotein (LDL)* - These are the largest lipoprotein in size. They carry 2/3 to 3/4 of all cholesterol in the plasma. Half of their density is composed of cholesterol. They are often called “bad” cholesterol because too much LDL can lead to buildup of cholesterol in artery walls. LDL is calculated using a formula after determining the measurement of the total cholesterol, HDL cholesterol and triglycerides. Measuring triglycerides requires a 12-hour fast.

$$LDL = Total\ cholesterol - HDL\ cholesterol - (triglycerides/5)$$

The NCEP has recommended the following guidelines for LDL cholesterol in adults:

<100 mg/dl = Optimal
 <100 - 129 mg/dl = above optimal
 <130 - 159 mg/dl = borderline high
 <160-189 mg/dl = high
 >190 mg/dl = very high

- (3) Recent guidelines (NCEP, 2004) are often based on patients’ risk, as determined by risk factors. In these cases the following levels are suggested:

For persons at **high risk** for heart disease (heart patients, post-surgical) a level of 100 mg/dl is recommended.

For persons at **moderate** risk a level of <130 mg/dl is recommended

For persons at **low risk** a level of <160 is recommended.



- b. The other lipoproteins include:
 - (1) *Chylomicron* - These are very large particles consisting of triglycerides. They are derived from the intestine and are produced by dietary fat.
 - (2) *Very Low Density Lipoprotein (VLDL)* - These are large particles consisting mainly of triglycerides. They are derived from the intestine and produced by dietary fat.
 - (3) *Intermediate Density Lipoprotein (IDL)* - These particles are smaller than VLDL and contain equal quantities of cholesterol and triglycerides. They are eventually converted to LDL.
4. *Atherosclerosis:* It is a form of “arteriosclerosis”. Atherosclerosis is characterized by atherosclerotic plaque which is a buildup of cholesterol, fat and other blood components deposited just beneath the inner lining of the arteries. As atherosclerosis progresses the arteries narrow, resulting in oxygen-rich blood and nutrients having difficulty reaching the heart, brain, lungs and other vital organs.
5. *Triglycerides:* They are the principle lipid found in fat deposits in the body. Triglycerides in blood are actually in transit to various sites of storage, or they are utilized by the body. They are made up of saturated and unsaturated fatty acids. The National Institutes of Health (NIH) Consensus Development Conference on Treatment of Hypertriglyceridemia has set the following guidelines for fasting triglyceride levels:
 - <150 mg/dl = normal triglycerides
 - 150-199 mg/dl = borderline Hypertriglyceridemia
 - >200 mg/dl = definite Hypertriglyceridemia

D. Initial Classification and Recommended Follow-up

1. Classification Based on Total Cholesterol
 - a. Desirable (less than 200 mg/dl)
 - b. Borderline (200-239 mg/dl)
 - c. High (240 mg/dl or 200-239 mg/dl with 2 coronary heart disease risk factors*)
2. If client has personal history of CHD (MI, angina, coronary bypass surgery, or other occluded vessel treatment) he/she is classified as high risk.
3. *Other CHD risk factors must be considered when determining classification (See



Appendix A):

- a. Male gender ≥ 45 years
 - b. Female gender ≥ 55 years, or premature menopause without estrogen replacement therapy
 - c. Diabetes Mellitus
 - d. Current cigarette smoking
 - e. Hypertension
 - f. Low level of high density lipoprotein (HDL): <35 mg/dl
 - g. History of definite cerebrovascular or occlusive peripheral vascular disease
 - h. Family history of premature CHD. Before age 55 in father or brothers. Before age 65 in mother or sisters.
4. Risk factors not considered in determining classification. (however they are CHD risk factors)
- a. Obesity (Body Mass Index (BMI) ≥ 30 kg/mg²)
 - b. Sedentary lifestyle
5. Verification
- a. Classification must be verified and based on the average of two cholesterol measurements within a 1 to 8 week time frame, provided the range between the two tests does not exceed 30 mg/dl. If the difference exceeds 30 mg/dl, a third test must be obtained and the three tests averaged.
 - b. Repeat any total cholesterol value less than 100 mg/dl or greater than 300 mg/dl. If repeated test exceeds 300 mg/dl, see Classification of High Risk Families section.
 - c. Repeat any HDL measurement less than 15 mg/dl or greater than 100 mg/dl. This is mainly to ensure you are not reporting a falsely high or low reading.
 - d. Schedule and/or notify participants at screening of follow-up dates for verification of total cholesterol or HDL tests out of desirable ranges.
6. Recommended Follow-up
- a. Desirable: Total Cholesterol less than 200 mg/dl. Provide dietary and exercise information and recheck within 5 years.
 - b. Borderline:** Total Cholesterol 200-239 mg/dl without definite CHD or two other risk factors. Provide dietary and exercise information and recheck annually.
 - c. High Risk:** Total Cholesterol 200-239 mg/dl with definite CHD or two other risk factors. Lipoprotein analysis and further action is based on LDL cholesterol value.

OR:



Total Cholesterol 240 mg/dl or greater. Provide or refer for lipoprotein analysis and further action based on LDL cholesterol value.

*** Levels must be verified before initiating follow-up.*

High Risk Families

- d. Persons with strong family history of CHD before the age of 55 in males, or before the age of 65 in females (two or more cases of early CHD in first degree relatives)
- e. Persons who themselves had premature CHD under the age of 55 if male or under the age of 65 if female
- f. Primary lipid disorders
 - (1) Familial hypercholesterolemia is defined by two or more first degree relatives (parent, offspring, brothers and sisters) with serum total of LDL cholesterol above the 95th percentile for age.
 - (2) Familial combined hyperlipidemia is characterized by elevations of total cholesterol, triglycerides, or both, in at least three first degree relatives.
 - (3) Adults with a verified reading greater than 300 mg/dl are at high risk and should follow steps 4 and 5 below.
 - (4) Test family members
 - (a) Recommend testing total cholesterol and triglyceride for high risk families including offspring and siblings of adults tested.
 - (b) Verify family members results following guidelines.
 - (c) Children are considered borderline if greater than the 75th percentile and high risk if greater than the 95th percentile.
 - (5) Follow-up Recommendations
 - (a) Refer high risk families to their personal physician.
 - (b) If they don't have a personal physician or want referral to a lipidologist, contact the University of Utah Cardiovascular Genetics Research Clinic at: (801) 581-3888.

7. Recommendations for Persons with Diabetes

- a. Coronary heart disease mortality is two to four times higher in diabetic than in non-diabetic individuals.
- b. People with diabetes often have lipid disorders due to poor metabolic control and its effects on lipoprotein metabolism.
- c. Hypertriglyceridemia is associated with poor diabetes control and obesity. In the insulin dependent diabetic (IDDM), triglyceride levels may be elevated due



- to a reduction in lipoprotein lipase activity. In the non-insulin dependent diabetic (NIDDM), elevated triglyceride levels may be due to an over-production of VLDL by the liver.
- d. Hypercholesterolemia is also seen in persons with diabetes. Some of the excess cholesterol may be from the body's metabolism of triglycerides and inability to absorb lipoproteins.
 - e. In most cases, hyperlipidemia associated with diabetes can be improved by tightening glycemic control.
 - f. Classification of persons with diabetes by LDL level:
 - (1) <200 mg/dl - Desirable
 - (2) >200 mg/dl - High risk
 - (3) There is no "borderline high risk" category for persons with diabetes
 - g. Follow-up and referral based on total cholesterol:
 - (1) Desirable - Recheck in 1 year
 - (2) High risk - Recheck in 1 to 8 weeks. If still elevated, refer to medical doctor for evaluation of glycemia control and fasting lipoprotein analysis.



II. CHOLESTEROL SCREENING AND MEASUREMENT

A. Planning for a Cholesterol Screening

Since the initiation of the National Cholesterol Education Program (NCEP) and the development of simpler, more rapid laboratory measurements of cholesterol levels, screening for blood cholesterol level has become widespread. Public screening has the possibility of detecting large numbers of individuals with high blood cholesterol levels in addition to those detected in the physicians's office. Public screening is effective in detecting high blood cholesterol in individuals who might otherwise not be identified by the health care system and ensures follow-up on appropriate cases and public education about cholesterol. Primary emphasis should be given to the target population 18-60 years old. Access to these individuals may be better served by targeting the worksite or specific community settings.

1. Objectives for Public Cholesterol Screening

- a. To detect individuals with high levels of total blood cholesterol, low levels of HDL and high levels of LDL, and make appropriate referrals to sources of medical care.
- b. To raise public consciousness and knowledge about CHD and blood cholesterol.
- c. To provide information about eating patterns and healthy lifestyles to achieve and maintain appropriate levels of blood cholesterol.
- d. To reach those who might not otherwise have their blood cholesterol measured as part of routine health care.

2. Recommendations for Public Screening

Public screening must meet customary standards for recruitment, reliable measurement of cholesterol level, appropriate information, staff training, and referral. Public screening programs should:

- a. Use recruitment approaches that attract all adult segments of the community, and develop special approaches to reach target groups. These include men, younger adults, low-income or low-education groups, and minorities.
- b. Ensure precise and accurate cholesterol measurements. Public screening should meet the standards defined by the Laboratory Standardization Panel of the NCEP, CLIA '88 (Clinical Laboratory Improvement Act of 1988) and OSHA (Occupational Safety and Health Administration). Laboratory instruments to measure cholesterol should undergo pre-field evaluation and should be subject to an ongoing system of quality control.



- c. Include education as part of screening by providing reliable verbal and printed information about cholesterol levels from knowledgeable staff. Only telling a participant his or her cholesterol number, without including education, is not sufficient in a screening program.
 - d. Ensure well-trained, carefully supervised staff members who have received training specific to their responsibilities, have access to consultation from appropriate health professionals, and have adequate supervision.
 - e. Come registered under the CLIA '88 program, and be in complete compliance with all related requirements.
 - (1) Apply for a certificate of waiver through the State Lab.
 - (2) Keep machines up to date and use only Cholestech LDX for testing.
 - (3) Be registered with an acceptable proficiency testing program, which includes at least three testing sessions per year.
 - f. Maintain an environment conducive to effective public screening by establishing liaisons with community health care resources. Screening sites should be convenient, efficiently accommodate the numbers of clients, and be designed to ensure quality-control procedures.
 - g. Provide cholesterol screening at a reasonable cost to the participants.
 - h. Provide active referral and follow-up programs. The screening agency should be responsible for taking steps to increase the likelihood that referred clients reach medical care. Follow-up methods such as letters or telephone calls are necessary.
 - i. Recommend referrals on the basis of the NCEP guidelines.
 - j. Provide blood pressure measurement at all cholesterol screenings since elevated blood pressure is also one of the primary factors for coronary heart disease.
3. Clinic Screening
- a. Preparation for a small community clinic setting, though similar to a large screening, has some differences in layout.
 - b. Planning for a cholesterol screening in a clinic situation is dependent upon the needs and resources of the screening organization.
 - c. The screener organization can utilize the information given for large community settings and plan their clinic screening based on these principles and their own identified needs and resources.
4. Community Screening
- a. Choose a setting to access the target population.
 - b. The worksite, such as an industrial setting or offices, are ideal for not only reaching the target population but for follow-up and education.



- c. General community screening such as in malls or shopping centers, will reach a larger proportion of the elderly. In addition, follow-up is very difficult as well as costly.
- 5. Publicity
 - a. A successful screening must include a publicity campaign to advertise, market and explain the purpose of the screening. Information on location, day, time, and cost is included in the promotional material.
 - b. There are a number of clients who arrive half an hour to one hour before the scheduled time. There are also some who arrive at the last minute. It is suggested to either make it clear that the screening cannot begin until the scheduled time, or actually plan to start half an hour before the publicized time. Regarding closing, publicize the closing time as half an hour earlier than the intended closing time. Don't admit any more clients into the screening.
- 6. Planning tips
 - a. Determine the number of analyzers and staff needed to conduct a screening.
 - (1) One Cholestech LDX can screen approximately 12 clients/hour.
 - b. Draw a sketch, or plan of the room to include the following stations: waiting area, sample collection, analyzers, blood pressure measurement, repeat blood pressure measurement, and results/education.
 - c. For machines to operate correctly the temperature must be between 59-90 degrees F, and the humidity no greater than 85%.
 - d. Avoid direct sunlight.
 - e. The analyzer should be at least 6 ½ feet away from any high frequency, ultrasound instruments, or low frequency emitters, such as centrifuges.
 - f. A grounded wall outlet must be available for each analyzer, or an extension cord.
- 7. Physical Set-up and Equipment
 - a. Provide sufficient chairs and tables to accommodate clients in the sign-up, testing and education areas.
 - b. Receptacles for both biohazardous and non-biohazardous waste must be available.
 - c. A separate table for blood pressure testing is necessary to prevent noise interference when the screener is listening to determine the blood pressure.
 - d. Ensure there are enough outlets (two machines per outlet) with three pronged grounded plugs or an adapter that converts two prongs to three prongs.



B. Preparation for Cholesterol Measurement

1. Staff
 - a. Qualifications
 - (1) All screeners must be standardized by the Utah Department of Health (UDOH), Cardiovascular Program (CVP) or a clinical affiliate.
 - (2) All testing personnel must have a high school diploma, or documented training in testing and laboratory techniques.
 - b. Appearance
 - (1) All staff should wear clean, pressed lab coats, or other authorized clothing.
 - (2) Lab coats should only be worn in testing areas, and removed before leaving the area.
 - (3) Identification tags should be worn.
 - c. Positions
 - (1) One registrant to take money, pass out forms and check the forms for completion.
 - (2) One individual to perform finger sticks for up to four machines.
 - (3) One individual to operate up to four analyzers.
 - (4) Two or three screeners to do blood pressure checks and rechecks.
 - (5) One or two individuals to do education.
2. Equipment
 - a. Analyzers and Related Equipment
 - (1) Cholestech LDX is a portable analyzer capable of processing several different tests; It has been approved for “waived” status under CLIA ‘88.
 - (a) The tests utilized by the Cardiovascular Program include total cholesterol, HDL, glucose, triglyceride, and lipid panel.
 - (b) The analyzers can process one sample in about 7 minutes.
 - (c) These machines are used as a screening tool, **not** as a diagnostic tool.
 - (2) Control sera



- (a) Have at least one of each level of suitable control sera. In case the control results are not in the acceptable ranges, a second bottle of each control is necessary to rerun controls. Results in the acceptable ranges are of utmost importance to assure accurate client results.
 - (b) Have cassettes suitable to machines being used for testing. A portion of these will be used for quality control. Transport them in coolers with packaged ice or “blue ice.”
- (3) Extension cords
- (4) Surge Protector Cord (to accommodate all analyzers)
- (5) Operators manual
- b. Blood Sample Collection Materials
 - (1) Capillary tube plungers used for Cholestech LDX
 - (2) Capillary tubes (use only those appropriate to the test being performed)
 - (3) Lancets (spring-loaded and disposable for each specimen to be collected)
 - (4) Gloves - Use intact latex (include enough to be changed between each client)
 - (5) Alcohol swabs
 - (6) 2x2 gauze squares
 - (7) Band-Aids (must be applied to every finger stick or needle stick)
 - (8) Impervious towels (Use one where the finger sticks will be done and one in front of the analyzers where the sample is pipetted onto the reagent. Have several available to replace used ones as they become soiled with blood)
 - (9) Biohazard containers (sharps container and bag for each specimen collector & analyzer operator)
 - (10) Ammonia ampules (for clients who may become lightheaded)
 - (11) Organizer (useful for storing blood draw equipment)
- c. Other
 - (1) Table cloth (one for each table with analyzer and one for each specimen collection table, disposable or washable preferred)
 - (2) Lab coats and name tags for all personnel
 - (3) Trash containers and liners (for trash that is not contaminated)

C. Procedure for Blood Sample Collection (Finger stick)

Since the collection of the patient’s specimen is the beginning of the analytical process, the use of proper collection techniques is essential to the quality of service offered in the point of care laboratory. It is imperative that laboratories follow universal precautions and safety



procedures. Many laboratory errors can be traced to such non-analytical factors as misidentifying or mishandling specimens. Non-analytical error can be prevented by using careful collection and processing procedures.

1. Patient Preparation and Site Selection

- a. Identify and notify patient of pre-test requirements, i.e., fasting for triglycerides.
- b. The patient should sit quietly for 5 minutes before the blood sample is collected.
- c. The side of the palmar surface of the middle or ring finger of either hand is the preferred site. A site on the side at the end of the finger should be selected that has few nerve endings and is not callused or scarred. The site should be warm to the touch.
- d. To increase blood flow to the site, wash the patient's hand with warm water or apply a warm compress at a temperature no higher than 42 degrees C (108 degrees F) to the hand for several minutes.

OR

Gently massage the finger from the base to the tip of the finger before but not during the collection of the sample.

2. Procedure

- a. Clean the site with a 70% isopropyl alcohol swab. Dry thoroughly with a sterile gauze pad. Leaving alcohol on the site causes rapid hemolysis.
- b. Prepare the apparatus that will be used to draw the capillary blood after the finger stick procedure.
- c. Prick the selected site with a lancet.
- d. Wipe away the first drop of blood with gauze as it may contain excess tissue fluid.
- e. Gently press the area around the puncture site until a large drop of blood forms. Hold the puncture site downward and gently apply pressure to the surrounding tissue. This will make the blood flow more freely. Do not milk the finger.
- f. Collect the sample using the method you have chosen to perform the test. When using a capillary tube be sure to avoid air bubbles during sample collection by holding the capillary tube horizontally.
- g. If an air bubble occurs, dispose of the capillary tube and use a new one. Wipe off any excess blood from the finger and have the patient apply pressure to the puncture site with a clean sterile gauze pad until the bleeding stops. Apply a band-aid to all puncture sites.

Note: When performing a finger stick for a cholesterol test, it is important to note that excess squeezing (or "milking") of the puncture site may cause



hemolysis or dilute the specimen with tissue fluid which may produce erroneous results.

D. Procedure for Venipuncture

1. Preparation of Site

- a. Client must sit 5 minutes prior to the venipuncture. Cholesterol values are altered depending on whether the client has been sitting, lying or standing.
- b. Client must sit during venipuncture.
- c. Intact gloves should be used by person(s) performing venipuncture.
- d. Reassuring the patient: The venipuncturist must have the patient's confidence and assure them that, though the procedure will be uncomfortable, it will be short in duration. It is wise to tell the patient when the needle enters the skin so as not to frighten him/her as they will feel a slight prick. Patients should never be told "This won't hurt."
- e. Ask the patient to be seated comfortably in a chair. Have the patient position his/her arm on the armrest, extending the arm so as to form a straight line from the shoulder to the wrist. The arm should be supported firmly by the armrest and should not be bent at the elbow.
- f. Check to make sure the tube has been labeled properly with the patient's name or number to avoid mistakes or confusion in processing.
- g. Ask the patient to close his/her hand. The veins become more prominent and easier to enter when the patient forms a fist. Vigorous hand exercise (pumping) should be avoided.
- h. Vein selection: Although the larger and fuller median cubital and cephalic veins are used most frequently, wrist and hand veins are also acceptable for venipuncture.
- i. Palpate and trace the path of the veins several times with the index finger. Unlike veins, arteries pulsate, are more elastic, and have a thick wall. Thrombosed veins lack resilience, feel cord-like and roll easily.
- j. If superficial veins are not readily apparent, blood can be forced into the vein by massaging the arm from wrist to elbow. Tapping sharply at the vein site with index finger a few times will cause the vein to dilate. Lowering the extremity will also help the veins to fill to capacity.
- k. Many times, veins in the opposite arm will prove suitable for venipuncture.
- l. Cleanse the venipuncture site.
 - (1) Cleanse the site with a circular motion from the center to the periphery.
 - (2) Allow the area to dry to prevent hemolysis of the specimen and a burning sensation to the patient when the venipuncture is performed.
 - (3) If the venipuncture proves difficult and the vein must be touched again in order to draw blood, cleanse the site again.



- m. Use a tourniquet to increase venous filling, which makes the veins more prominent and easier to enter.
 - (1) Never leave the tourniquet on longer than 1 minute, or a variation in the test value may result.
 - (2) If a tourniquet must be applied for the preliminary vein selection, it should be released and reapplied after waiting 2 minutes.
 - (3) Wrap the tourniquet around the arm 3 to 4 inches above the venipuncture site. Tuck the end under the last round. If a velcro tourniquet is used, adhere the tabs to each other.
- n. Grasp the patient's arm firmly, using your thumb to draw the skin taut. This anchors the vein. The thumb should be 1 or 2 inches below the puncture site.

2. Venipuncture Technique

- a. Thread the appropriate needle into the holder until it is secure, using the needle sheath and a wrench.
- b. Insert the blood collection tube into the holder and onto the needle up to the recessed guideline on the needle holder. Do not push the tube beyond the guideline, as a premature loss of vacuum may result. The tube will retract lightly. Leave it in this position.
- c. Make sure the patient's arm or other venipuncture site is in a downward position while maintaining the tube below the site when needle is in vein during the procedure. This will help insure that no backflow from the tube will go into the patient's vein.
- d. Perform the venipuncture.
 - (1) The needle should be at approximately a 15 degree angle to the patient's arm and in a direct line with the vein.
 - (2) Turn the needle so that the bevel is in an upward position.
 - (3) The puncture of both the skin and the vein should be done, if possible, in one motion.
 - (4) Grasp the flange of the needle holder and push the tube forward as far as it will go.
 - (5) Steady the needle holder so the needle is not inadvertently removed from the vein, causing a "short draw."
 - (6) Remove the tourniquet as soon as blood flow is established. Once the draw has started, do not change the position of the tube until it is withdrawn from the needle. During the procedure, do not allow the contents of the tube to contact the stopper. Movement of the fluid back and forth in the tube can cause back-flow of blood into the venous system, with the possibility of adverse patient reaction.
 - (7) Have the patient open his/her hand.



- (8) Fill the tube until the vacuum is exhausted and blood flow ceases. This will ensure that there is a correct ratio of anticoagulant to blood. It is normal for the tube not to be completely filled.
- (9) When the blood flow ceases, remove the tube from the holder. The shut-off valve re-covers the point, stopping blood flow.
- (10) Lightly place the gauze pad above the venipuncture site.
- (11) Apply slight pressure to the pad. Remove the needle slowly while keeping the bevel in an upward position. Exercise care not to scratch the patient's arm.
- (12) Slip the gauze pad down over the site, continuing mild pressure.
- (13) Apply an adhesive gauze bandage over the puncture site after making sure that bleeding has stopped.

3. Precautions

a. If a blood sample is unobtainable:

- (1) Change the position of the needle. If it has penetrated into the vein too far, pull it back a bit. If it has not penetrated far enough, advance it farther into the vein. Rotate the needle a half a turn.
- (2) Try another tube. The tube used may not have had sufficient vacuum.
- (3) Loosen the tourniquet. It may have been applied too tightly, thereby stopping the blood flow. Reapply the tourniquet loosely. If the tourniquet is a velcro type, quickly release and press back together.
- (4) Probing is not recommended. This is painful to the patient. In most cases, another puncture in a site below the first site is advised.
- (5) It is advisable not to attempt a venipuncture more than twice. Have another person attempt to draw the specimen or notify the physician.

b. Dispose of the needle by lying the shield on a table and slipping the needle back into it. Do not hold the shield in your hand to do this, or you are increasing the possibility of sticking yourself with a contaminated needle.

E. Processing the Blood Sample

Blood is processed using the Cholestech LDX analyzer. Follow the procedure suggested in the Cholestech LDX User Manual.

F. Closing the Clinic

1. Schedule closing time for half an hour before staff are scheduled to leave to avoid staying later than planned.
2. Clean instrument as outlined in owner's manual.
3. Wipe off entire table cloth if necessary, or discard if soiled.



4. Remove trash receptacle liners and place in biohazard bags.
5. Dispose of controls in biohazard container if they are expired.
6. If transporting and/or storing machines and supplies, ensure temperature is in recommended ranges.
7. Keep copies of the following documents on file in your individual laboratory:
 - a. Quality control log form
 - b. Optical system performance check log
 - c. All proficiency testing results
 - d. Any incident reports submitted



III. QUALITY ASSURANCE

A. Cholesterol Measurement Variability

Even when appropriate quality control and staff training are optimal, analyte and biologic variability will lead to some misclassification of individuals. *If staff training and quality control are less than optimum, up to 25% or more of the screenees may be misclassified.* Therefore it is imperative to stress that a single cholesterol measurement, even with the most strenuous quality control, does not classify the individual as having high blood cholesterol. *Individuals possess their own personal variations with fluctuations in total cholesterol averaging around 10-15%.* Clients need to be notified of the possibility of variation in their cholesterol values. It is necessary to obtain a number of values to identify an overall trend.

1. Biological (more than 60% of variability results from these factors)

Factor	Effect	Amount of Variability
<i>Age/Gender</i>	Increased LDL	In men, increase of 30 mg/dl from young adult to middle age In women, the rise is most prominent after menopause
<i>Weight Reduction</i>	Decrease in total cholesterol Increase in HDL	Weight reduction in an obese individual usually results in a small decrease (<10%) in total cholesterol and an increase in HDL Triglycerides will vary the most, up to 40% Repeated weight gain and loss is a source of variation of total cholesterol measurements
<i>Genetic</i>	May increase or decrease any of the factors (HDL, LDL, triglycerides, total cholesterol)	Primarily apolipoprotein-receptor-mediated metabolism accounts for 45% of variation
<i>Daily Weekly Seasonal</i>	Lipid concentration for the December - January period may be up to 2.5% higher than those measured in June for total cholesterol	Daily - up to 2.5% Weekly - up to 4.8% Seasonal - up to 6.1%



2. Clinical (amount of variability is unknown at this time)

Factor	Effect
<i>Recent Myocardial Infarction</i>	Variable decrease in total cholesterol and LDL but returns to normal after 2 months
<i>Inflammatory or Infectious Illness</i>	Decrease in total cholesterol and HDL Increase in triglycerides
<i>Propranolol</i>	Decrease HDL and total cholesterol Increase in triglycerides
<i>Diuretics</i>	Increase total cholesterol and triglycerides Small decrease in HDL
<i>Combined Therapy- Propranolol/Diuretics</i>	Substantial decrease in HDL
<i>High Vitamin Intake/Sedatives (i.e. phenol-barbitol)</i>	Causes variability in total cholesterol
<i>Pregnancy/Lactation</i>	Slight decrease of total cholesterol in the first trimester Continuous increase through the second and third trimesters (Increase is mainly due to increased LDL) If not lactating, measure cholesterol after 3-4 months postpartum
<i>Chronic Disorders (such as hypothyroidism, obstructive liver disease, kidney disease, etc.)</i>	Total cholesterol and LDL can be increased
<i>Oral Contraceptives</i>	Raise LDL levels, and lower HDL levels
<i>Steroids</i>	May increase total cholesterol
<i>Stroke/Surgical Trauma</i>	Exact effect has not yet been defined
<i>Menstrual Period</i>	Decrease in LDL Increase in HDL



Factor	Effect
<i>Estrogen</i>	Total cholesterol is more labile in women who are using estrogen than in those who are not. It may raise HDL levels. When progestins are added, the HDL is reduced. Estrogen replacement therapy, both with and without progestins, lowers the total cholesterol value.

3. Behavioral (most of variability for several of the factors is unknown at this time)

Factor	Effect	Amount of Variability
<i>Diet</i>	The individual's response to dietary changes will vary. The rate of response could be predicted by the caloric, saturated fat and total fat intake in the diet.	Those who do not respond to diet only vary about 3% Those who do respond to dietary changes may vary up to 9%
<i>Alcohol</i>	Increases HDL3, and triglycerides. According to recent research, high HDL2 (A subfraction of HDL) has been associated with lowering CHD risk. HDL3 (another subfraction of HDL) is not associated with this protective mechanism.	
<i>Exercise</i>	3 hours prior to measurement will effect total cholesterol	May increase total cholesterol value by 6% May increase HDL and decrease LDL over time
<i>Smoking</i>	It increases LDL and triglycerides, and decreases HDL, over time Does not affect the measurement results	
<i>Caffeine</i>	Will affect measurement results by increasing total cholesterol concentration It will increase LDL over time	



Factor	Effect	Amount of Variability
<i>Excess Fluid</i>	Affects total concentration levels of LDL if excessive fluid is ingested 2-3 hours before a measurement	

4. Sample Collection (amount of variability is unknown at this time)

Factor	Effect
<i>Blood drawn from a standing position</i>	Is more dilute and will result in a lower cholesterol level

5. Laboratory - Variations of the client's cholesterol value can also occur as a result of laboratory factors. This is primarily due to equipment, supplies and/or screener technique.
- Equipment: The screener organization's use and maintenance of the equipment is paramount to accuracy of the client's cholesterol measurement. Equipment use must be according to the manufacturer's recommendations. Quality control must be performed to ensure proper working order of the equipment at the time of the screening.
 - Supplies: Defective cholesterol reagents have the potential for altering the cholesterol value. This could be a result of manufacturer's error, temperature extremes during storage, or screener mishandling. The screener organization will need to perform quality control checks on the reagents as well as observe each reagent after processing to lessen the potential for error.
 - Screener Technique: Reliable laboratory measurement of total cholesterol is dependent on the screener's methods and adherence to quality control procedures. Inaccurate measurement may lead to clinical misdiagnosis because of the reporting of false positive or false negative values. Because errors in measurement most often originate from poor sampling methods, it is imperative that all screeners undergo training and certification by the Utah Department of Health, Cardiovascular Program (UDOH/CVP) prior to involvement in cholesterol screening. Portable analyzers for cholesterol measurement, and the relationship of elevated cholesterol as an increased risk for cardiovascular disease are new sciences. Therefore, it is not enough for all screeners to become certified, they must continue to be updated on new information and data available through the Utah Department of Health.
 - Environment: There is some clinical evidence that indicate the cholesterol reagent strips and the analyzers may be effected by environmental factors such as heat, cold, and humidity. All cholesterol supplies include an indication of acceptable storage temperature ranges. These must be adhered to while in the



- clinic, traveling, or at the screening site. The screener needs to be aware of the possibility of errors due to faulty strips and retest any individual whose value is very high, very low, or not in accordance with their expected level based on previous cholesterol values, medical history, risk factors, etc.
- e. Technology: Accuracy, agreement with the true value, is also essential to a reliable analytical system. Quantitative measurements are relative in nature; that is, the measurements are based upon comparison with a reference material with a known concentration of analyte that has been previously established by a reference and/or definitive method. A variety of cholesterol measurement methods are in use, each having unique performance characteristics. The use of different methods (each based on different analytical principles, or which use different reagents, calibrators, and instruments) can lead to inaccuracy or biases. *Laboratories must give special attention to methods and calibration procedures to minimize the method-instrument-specific biases.* Inaccurate measurement may lead to clinical misdiagnosis because of the reporting of false positive or false negative values. For example, a laboratory that measures cholesterol with a method having a positive bias of 10% at a medical decision point of 200 mg/dl would report the falsely high value of 220 mg/dl. With the same percentage bias at the 240 mg/dl decision point for high risk (Table 1), the laboratory would report a falsely high cholesterol result of 264 mg/dl. Thus, the higher the true concentration of the blood cholesterol, the greater the absolute magnitude of the error; this magnifies the unreliability of the values. The Laboratory Standardization Panel recommends that biases in methods presently in use should not exceed $\pm 5\%$ from the true value and that ultimately, a national goal of $<\pm 3\%$ bias should be achieved. It is not uncommon for clinical laboratories in the United States to have cholesterol-method biases exceeding $\pm 5\%$ to $\pm 10\%$, or even $\pm 15\%$ or more. The Clinical Laboratory Improvement Act of 1988 requires all laboratories to enroll in an approved Proficiency Testing Program in order to monitor the accuracy of each laboratory engaged in cholesterol testing.

B. Quality Control

1. Purpose - To ensure accuracy (agreement with a true or known value) and precision (freedom from inconsistency or random error during repeat measurements) of cholesterol test results.
2. Personnel
 - a. All persons who perform cholesterol testing must have a high school diploma or documented training in cholesterol testing and laboratory techniques.
 - b. All screeners must be standardized by the UDOH/CVP or trained personnel and attain 80% accuracy on the written test.
 - c. Complete a practicum by performing two separate finger stick tests on the same individual and achieving results within $\pm 3\%$, to quantitatively check



technical skills.

3. Instrumentation

In addition to operator considerations, all equipment and supplies used to test cholesterol should be in proper working order.

- a. The instrument's optical system should be checked daily (or when used) by methods suggested by the instrument manufacturer. This checks the internal spectrometer and is the only test of this kind recommended by the manufacturer. Values for all wavelengths should be documented on the Quality Control Form and monitored by the program staff.
- b. Controls with test cholesterol levels close to the NCEP Adult Treatment Guideline cut points are preferred. One normal (approximately 180-190 mg/dl) and one clinically relevant (approximately 240-250 mg/dl) test sample should be run at the beginning of each screening day and each time the machine is turned off and then back on again.
- c. All potential sources of error should be examined if one of the two controls is not within the acceptable range. The control test should be run again using a fresh control serum. If the test is still outside the acceptable range, the instrument should not be used. Likewise, if one of the wavelengths of the optical eye is out of the acceptable range, the machine should not be used until the problem is corrected.
- d. All results are to be recorded on the appropriate forms and kept in a log book. All remedial action should be documented and reviewed by the laboratory director.
- e. Any incidents pertaining to testing or phlebotomy should be noted in the "notes" section on the bottom of the Quality Control Sheet and communicated to the laboratory Director.

C. Proficiency Testing

1. The Utah Department of Health, Cardiovascular Program requires all laboratories to be registered with a proficiency testing program. Below is one suggestion for a reliable proficiency testing program:

MedTek
8619 W. Sandy Parkway
Draper, Ut 84070
Phone: 1.801.561.3339

2. Under "waived" status by CLIA '88, two samples are tested and results are reviewed by WSLH. Results are then returned to UDOH/CVP and entered in the Quality Assurance Log. This testing occurs three to four times annually, in compliance with state requirements.



D. Calibration

1. Machines should be calibrated yearly.
2. One machine can be designated as the “base” machine, and all other machines can be compared to this machine.
3. Machine comparisons should be made every six months and results recorded on appropriate form in Quality Assurance Log.
4. Acceptable materials can be obtained from: MedTek, Phone: 1 801-561-3339
5. Results are calculated and recorded on the Instruments Calibration form and placed in the Quality Assurance Log.
6. If calibration results are unsatisfactory, Technical Services should be notified immediately, and machines should be returned for repair.

E. Screener Precautions

The Occupational Safety and Health Administration’s final rule regulating Occupational Exposure to Blood-borne Pathogens (CFR Part 1910.1030) requires all health care organizations to adopt an exposure control plan that is designed to minimize or reduce occupational exposure to blood and other potentially infectious materials, and to protect the health care worker by preventing blood-borne diseases such as infection with human immunodeficiency virus (HIV) or hepatitis B virus (HBV). This plan is included on the following pages. In addition to this plan, the UDOH/CVP has outlined precautions which apply specifically to cholesterol screening.

1. Supplies
 - a. Gloves
 - (1) Must be worn by all screeners handling controls or blood products.
 - (2) Must be intact latex.
 - (3) Must be changed with each new client.
 - (4) Do not wear colored fingernail polish under gloves. It may be mistaken for blood.
 - b. Needles and Lancets
 - (1) Shall not be recapped, purposely bent or broken by hand, removed from disposable syringes, or otherwise manipulated by hand.
 - (2) Place in a puncture-resistant biohazard container constructed so that



contents will not spill if knocked over. The container must be easily accessible to health care worker.

- (3) Preferable, impervious towels will be used in all areas where blood spills or droplets may occur. However, if blood spills occur elsewhere, cleaning should be done as follows:
 - (a) All blood spills or droplets and any possible contamination of tables, equipment, and the outside of BIOHAZARD containers must be cleansed with disinfectant.
 - (b) Disinfectant: a solution of 5.25 % sodium hypochlorite (household bleach) dilute between 1:10 and 1:100 with water or another suitable disinfectant.

2. Disposal

a. Containers

- (1) Puncture-resistant containers should be:
 - (a) Used for all blood contaminated products, e.g.: needles, lancets, and reagent strips/cassettes.
 - (b) Marked or tagged with the word BIOHAZARD or biological hazard or biological hazard symbol readable at a minimum distance of 5 feet.
- (2) Bags
 - (a) May be used for contaminated cotton balls, 2x2 gauze pads, gloves, paper towels, and Band-Aids.
 - (b) Should be double bagged where puncture or outside contamination is likely.
 - (c) Must be tied securely.
 - (d) Must be tagged with “BIOHAZARD” and/or identified by using red bagging.

b. Blood product disposal

- (1) Autoclave - sterile puncture resistant containers and double bags
- (2) Incinerator - high residue incinerator in compliance with OSHA standards
- (3) Secure landfill - defined as products that are protected and guaranteed not to reach the public while being transported from health care site to landfill and after deposit (Residual from the incinerator and autoclave are deposited in secure landfill)



F. Accidental Needle Stick Punctures

1. It is suggested that all employees involved in obtaining blood specimens or performing any laboratory test involving blood be immunized against Hepatitis B. The cost is the responsibility of the employer, and immunization is available at the Utah Department of Health.
2. Hepatitis B infection is a major infectious occupational hazard for anyone involved in obtaining blood specimens or performing any laboratory test involving blood. In the event a screener receives a needle stick puncture by a contaminated lancet, emergency medical treatment should be sought. Because the value of HBIG beyond 7 days after exposure is unclear, prophylaxis should begin as soon as possible after exposure. The incubation period for hepatitis is 45-160 days, and clinical signs of the infection may not appear for some time after initial exposure. The following medical emergency protocol should be followed:
 - a. Immediately draw a re-top-tube of blood from both the patient whose lancet was responsible for the puncture and the injured party, as well. (The law does not require that the patient give permission for this test, but professional courtesy dictates that he/she be informed of the purpose of drawing this blood sample.)
 - b. Take the tubes of blood to the closest lab and request the following tests be performed:
 - HIV
 - Hepatitis B surface antigen (HBsAg)
 - Hepatitis B core
 - Hepatitis A
 - c. Complete and submit a Worker's Compensation "Report of Injury" form to your employer. The Physicians Report of Injury form should also be completed and submitted directly to workers compensation.
 - d. If the injured party has already been vaccinated against Hepatitis B and an adequate level of anti-HBs has been demonstrated within the last 24 months, no treatment is necessary.
 - e. If the injured party has been vaccinated, but, his/her level of anti-HBs is inadequate, a HB vaccine booster dose is recommended.
 - f. If the injured party has not been vaccinated, obtain the HBIG vaccine (a regimen of two doses of HBIG, one given after exposure and one a month later is about 75% effective in preventing Hepatitis B) and begin the series of Recombivax. This vaccine is given by injection on three separate dates. The first two doses should be given one month apart, and the third dose, five



- months after the second. The HBIG and Recombivax should both be administered at the initial visit to the health care provider on the same day.
 - g. If the client's sample is HIV positive both the screener and the client will be notified by the Division of Epidemiology or the attending physician, and advice and counseling will be available.
 - h. If the client should refuse to have his/her blood drawn, the screener should have a baseline sample drawn as suggested above, and follow-up tests at three months and six months.
 - i. In the case that the injured party is pregnant, this same procedure should be followed. The attending physician should be notified of exposure, so that proper prophylaxis can be started on the infant immediately after birth if it is necessary.
- 3. Training
 - a. The Utah Department of Health regulatory test must be made available and an education program is provided and repeated annually, for every employee who might be exposed.
 - b. Training includes an explanation of the epidemiology of blood-borne diseases and their modes of transmission, the employers exposure control plan, the actions to take in emergency and the procedures for post-evaluation and follow-up.
 - c. The curriculum also covers methods to reduce exposure, the types of protective equipment and the basis for selecting them. Employees are informed about "the benefits of being vaccinated" and have the chance to ask questions. (The OSHA regulatory text is available from OSHA Publications, Room N3101, 200 Constitution Ave. NW, Washington, DC 20210)
- 4. In addition to this outline the Utah Department of Health, Division of Epidemiology has issued an Exposure Control Plan for the Division of Community and Family Health Services which requires that all personnel in that division be trained annually.

G. Personnel

- 1. Documentation of highest level of education of laboratory employees is included with employment records in the Human Resource Office of the Utah Department of Health.
- 2. Laboratory personnel and duties for the Utah Department of Health, Heart Disease and Stroke Prevention Program are as follows:
 - a. Laboratory Director - Ensure that laboratory provides quality service by overseeing the testing and recording of results to ensure that they are done with utmost precision and accuracy, and are in compliance with CLIA '88 standards.



- b. Testing Personnel - Any person so designated who has a high school diploma or documented training. Full list of personnel including education and certification dates should be kept in Quality Assurance Log.
3. Requirements for Cholesterol Testing Personnel Certification
- a. Personnel need a minimum of 2 hours of training consisting of classroom discussion and hands-on experience in setting-up and operating the analyzer, performing usual maintenance, and conducting appropriate education and counseling.
 - b. Personnel should have a minimum of one week of supervised field experience operating the analyzer before operating the analyzer alone.
 - c. Personnel must attain 80% accuracy on written test.
 - d. Personnel must demonstrate 100% proficiency in performing, recording and analyzing one optic check (where required) and Level I and Level II control tests.
 - e. Personnel must attain 100% proficiency in demonstrating two test procedures according to protocol. Observers will score each finger stick and test procedure according to Training Check List.
 - f. Personnel must perform two separate finger stick tests on the same individual and achieve results within $\pm 3\%$ accuracy.
 - g. Upon completion of these requirements, a certificate is awarded to each employee. Permanent records are also kept in the laboratory office.
 - h. Renewal is required of all testing personnel every two years. This renewal is accomplished by completing the Certification Review Test.



IV. COUNSELING AND EDUCATION

A. Education

1. Define cholesterol: A fatty wax-like substance circulating in the blood
2. Explain how cholesterol is transported: It is attached to a protein for transportation in the blood stream
3. Explain how cholesterol is produced: All the cholesterol necessary for normal body functions is produced by the liver and intestines (approx. 70%)
4. Explain the function of cholesterol:
 - a. Found in all cell walls and on the myelin sheath of nerves
 - b. Necessary for the production of bile acids, hormones, and Vitamin D
 - c. Plays a role in the repair of vessel walls (Cholesterol and other substances can form plaque in blood vessels)
5. Discuss the complications of high cholesterol:
 - a. If not controlled, excess cholesterol can lead to atherosclerosis, “hardening of arteries”
 - b. Atherosclerosis can lead to heart attack and stroke
6. Identify the major *modifiable* risk factors for coronary heart disease:
 - a. Hypertension
 - b. Smoking
 - c. High Cholesterol
 - d. Sedentary Lifestyle
 - e. Obesity (See Appendices B & C)
7. Define the classification of cholesterol levels and discuss the risk factors
 - a. Classification
 - (1) Desirable: less than 200 mg/dl (If initial reading is <200 mg/dl or the average of 2 or 3 readings in 1-8 weeks is < 200 mg/dl)
 - (2) Borderline: 200-239 mg/dl without 2 risk factors
 - (3) High Risk: 240 mg/dl or greater, or 200-239 mg/dl with 2 risk factors
 - b. Risk Factors



- (1) Male gender ≥ 45 years
Female gender ≥ 55 years, or premature menopause without estrogen replacement therapy
- (2) Family history of premature CHD (Before age 55 in father or brothers or before age 65 in mother or sisters)
- (3) Diabetes mellitus
- (4) Smoking
- (5) Hypertension
- (6) Low HDL-concentration (below 40 mg/dl)
- (7) History of definite cerebrovascular or occlusive peripheral vascular disease, or coronary artery disease

Note: Obesity: ≥ 30 Body Mass Index (BMI) and sedentary lifestyle are also risk factors for cardiovascular disease; however, they are not used to change cholesterol classification from borderline to high risk (See Appendix A).

8. Define HDL, LDL and triglycerides

a. HDL: high density lipoprotein

- (1) Also known as the “good cholesterol”
- (2) Should be equal to or greater than 40 mg/dl
- (3) Helps in the removal of LDL and other undesirable lipoproteins

b. LDL: low density lipoprotein

- (1) Also known as the “bad cholesterol” since it is the major atherogenic cholesterol component
- (2) Classification
- (3)
 - (a) Optimal: LDL < 100
 - (b) Near or above optimal LDL: 100-129 mg/dl
 - (c) Borderline high: 130-159 mg/dl
 - (d) High risk: ≥ 160 -189 mg/dl

c. Triglycerides

- (1) A type of plasma lipid made up of saturated and unsaturated fatty acids
- (2) The desirable level is < 200 mg/dl

9. Questions commonly asked during education are:



- a. “How accurate is this test?”
 - (1) Analyzer’s accuracy is within 3% of Centers for Disease Control (CDC) standards set for laboratory accuracy.
 - (2) An individual’s personal variation can be as much as 10-15% on the average from one measurement until the next.
 - b. “Do I need to be fasting to have this test performed?”
 - (1) Total cholesterol and HDL cholesterol measurements do not require fasting. They are affected only to a small degree by what the individual has eaten in the past 12 hours.
 - (2) Triglyceride measurement and LDL calculation (which requires a triglyceride measurement) are affected by food consumed in the previous 12 hours. Therefore, fasting is required when these test are to be performed.
 - c. “Why do values from laboratory measurements sometimes differ from values obtained through the use of a portable analyzer?”
 - (1) While accuracy is certainly a factor, other sources for the variance may include the following:
 - (a) Capillary samples may be up to 8.5% lower than serum samples due to variations in concentration.
 - (b) Different anticoagulants used in sample tubes may affect cholesterol concentrations.
 - (c) Venous occlusion caused by a tourniquet applied for longer than 1 minute may increase the value by 2-5%.
 - (d) Laboratory equipment may be calibrated by different standards.
10. Explain the necessity for verification of values
 - a. Retest values above 200 mg/dl within 1-8 weeks for verification.
 - b. Physiological fluctuations occur within 2-3 weeks.
 - c. Any total blood cholesterol variation or change of more than 30 mg/dl from previous test must be repeated.
 - d. If the second test has a variation of 30 mg/dl or more, a third test must be performed.
 - e. Average first and second readings. If a third reading is necessary, average it with the first and second readings.
 11. Define recommended follow up



- a. Refer to Section I, pages 3-6.
 - b. A total cholesterol of 300 mg/dl, or an HDL greater than 100 mg/dl or less than 15 mg/dl should be repeated.
12. Explain the recommended behavior changes for cardiovascular disease
- a. Fat intake should not exceed 30% of total daily caloric intake.
 - (1) Less than 10% of daily fat intake should be saturated fat, and the other 20% should be unsaturated fat.
 - (2) Explain the difference between the three types of fats:
 - (a) Monounsaturated Fats
 - i) Predominantly derived from oleic acid but are present in all animal and vegetable fats
 - ii) Liquid at room temperature
 - iii) Good sources are olive oil, canola oil, and peanut oil
 - (b) Polyunsaturated Fats
 - i) Mainly found in the form of linoleic acid in foods
 - ii) There are two types: W-6 which is found in vegetable oils, and W-3 (omega) which is found in fish - both types may reduce total cholesterol
 - iii) Liquid or soft at room temperature
 - iv) Good sources are corn, safflower, soybean, and sunflower oils. Seafood is also a good source
 - (c) Saturated Fats
 - i) The body converts saturated fats to chylomicrons thereby increasing LDL
 - ii) Solid at room temperature
 - iii) Animal fats are a major source of saturated fats and cholesterol including meats, butter, whole milk, cream, ice cream, and cheese
 - iv) Some plant oils are a source of saturated fats: palm oil, palm kernel oil, coconut oil, cocoa butter, and hydrogenated shortening
 - (3) Fat is necessary in the diet for normal growth, healthy skin, and energy. But too much fat can be unhealthy.
 - (4) Fat consumption is associated with the development of some types of



- cancers.
- (5) Review the National Cholesterol Education Program (NCEP)/ American Heart Association dietary recommendations to lower cholesterol (See Appendix D).
- (6) Dietary changes are recommended for all Americans by the NCEP and the American Heart Association.
- b. Dietary cholesterol should not exceed 300 mg/day
 - (1) The body makes cholesterol so it isn't actually needed in the diet.
 - (2) Cholesterol is only found in animal products (meat and dairy products).
- c. Tips to decrease saturated fat and cholesterol consumption
 - (1) Use more chicken and fish, which contain less saturated fat.
 - (2) Cook chicken without the skin and prepare meat by baking or broiling.
 - (3) Limit the intake of whole eggs to 2-3 per week.
 - (4) Use low-fat or nonfat versions of all dairy products. Examples would be nonfat or 1% milk, nonfat or lowfat yogurt, lowfat cheese or part skim mozzarella.
 - (5) Encourage the intake of at least 2 servings of fruit and 3 servings of vegetables per day for a total of 5 a day.
 - (6) Use lower fat and calorie mayonnaise, salad dressing and softer margarine.
 - (7) Emphasize that processed foods frequently contain coconut oil, palm oil, cocoa butter, etc which are high in saturated fat.
 - (8) Read labels carefully.
 - (9) Formation of dietary habits in the home will influence children and future generations in prevention of cardiovascular disease.
- d. Weight loss is recommended to achieve ideal body weight
 - (1) A lowfat diet is an excellent way to cut calories.
 - (2) Grams of fat are more highly caloric than other food sources (9 calories per gram of fat vs. 4 calories per gram carbohydrate or protein).
 - (3) Fat is more easily stored in the body than other sources of calories.
 - (4) Physical activity helps control weight.
- e. Physical Activity
 - (1) Adults should accumulate 30 minutes or more of moderate-intensity physical activity, such as brisk walking, on most days of the week (5 or more days).
 - (2) Physical activity may increase HDLs, decrease LDLs, decrease blood



pressure and increase weight loss.

- f. Smoking cessation: Recommend reputable smoking cessation programs and self-help programs

B. Counseling and Behavior Change Techniques

1. Establish rapport
 - a. Deal on personal level
 - b. Maintain eye contact
 - c. Listen attentively
 - d. Speak on their level
 - e. Establish a partnership
2. Assess and identify the client's needs
 - a. Ascertain medical history
 - b. Identify their knowledge and interest about nutrition and dietary practices
 - c. Assess their readiness, ability and motivation to modify behavior
 - d. Assess social support
 - e. Assess the family knowledge and attitude about cholesterol and behavior change
 - f. Use open-ended questions
3. Develop a plan of action
 - a. Provide knowledge and education
 - b. Assess dietary problem areas by dietary recall and food frequency analysis
 - c. Identify unhealthy dietary behaviors (e.g. frequent consumption of fried foods, high fat snack foods, frequent consumption of ice cream, etc.)
 - d. Assess frequency of physical activity
 - e. Identify existing positive health habits
 - f. Assist client with developing short term and long term goals
 - (1) Clients should choose the items they feel they will have the most success with
 - (2) To improve success, choose one or two items to work on for 2-3 weeks before choosing additional items
4. Implementation of interventions
 - a. Give homework assignments and/or worksheets to increase self-monitoring and self-responsibility



- b. Provide handouts, recipes, and instructions on shopping, cooking tips, reading labels, etc.
 - c. Reinforce successes
 - d. Have client write a contract with significant other and include short-term and long-term rewards
 - e. Ask for a return demonstration from client on changing recipes, reading labels, etc.
 - f. Practice difficult areas or situations through role playing
 - g. Anticipate and discuss future problems
5. Evaluation
- a. Document changes in behavior
 - b. Cholesterol reduction usually takes 3-6 months
 - c. Determine client's understanding and satisfaction with lifestyle changes

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REFERENCES

- American Diabetes Association. (1989, May). Position Statement: Standards of Medical Care for Patients with Diabetes Mellitus. Diabetes Care, 12(5); 365-368.
- American Diabetes Association. (1988). Physician's Guide to Insulin-Dependent (Type I) Diabetes: Diagnosis and Treatment.
- American Heart Association. Physician's Cholesterol Education Handbook.
- Centers for Disease Control. (1988, June 24). Morbidity and Mortality Weekly Report, 37 (24). U.S. Department of Health and Human Services, Public Health Service.
- Davis K. (1987, July). Oklahoma Lipid Research Clinic Cholesterol Screening Protocol and Training Manual. Oklahoma Lipid Research Clinic.
- Denke, M.A. And Grundy, S. (1989, February). Treatment of Diabetic Dyslipidemia. Biochemical Society Transactions, 17(1); 56-58.
- Dunn, F. L. (1988, November). Treatment of Lipid Disorders in Diabetes Mellitus. Med Clin North Am, 72(6); 56-58.
- Grundy, S., et al. (1989, September 1). Basis for Dietary Therapy. Circulation, 80; 729-738.
- Mayrniuk, M.D. (1989, May/June). Hyperlipidemia and Diabetes: The Role of Dietary Fats. The Diabetes Educator, 15(3); 258-264.
- Naito, H.T. (1988, November 4). How to Ensure Reliable Cholesterol Measurement. The Cleveland Clinic Foundation
- Naito, H.T., Stein, E.A. & Rifkind, B. (Moderator). (1988, November 9-11). The National Cholesterol Conference.
- National Cholesterol Education Program Adult Treatment Panel. (1987, October 5). "Cholesterol Treatment Recommendations for Adults, Highlights of 1987 Report." National Heart, Lung and Blood Institute.
- National Institutes of Health. (1986, July). Facts About Blood Cholesterol (NIH Publication No. 86-2696). U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health.
- National Institutes of Health. (1988, January). Current Status of Blood Cholesterol Measurement in Clinic Laboratories in the United States, A Report from the Laboratory Standardization Panel of the National Cholesterol Education Program. (NIH Publication No. 88-2928). U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health.
- NIH - National High Blood Pressure Education Program, JNC VI report 1997.
- "PreAnalytical Factors." (1988), 24. An excerpt from the National Cholesterol Education Conference. Washington, D.C.
- "Policy Statement: Indications for Cholesterol Testing on Children." American Academy of Pediatrics.
- Scholenfeld, G. (1989, February). Lipoproteins and Atherosclerosis in Diabetes Mellitus. Biochemical Society Transactions, 7 (1); 53-55.
- Schucker, B. (1989 January 10). Recommendations Regarding Public Screening for Measuring Blood Cholesterol: Summary of a National Heart, Lung and Blood Institute Workshop. U.S. Department of Health and Human Services.

